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OCT 11 2005

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,464,864

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,464,864, which claims the human drug product FROVA® (frovatriptan succinate) and methods of using the human drug product FROVA® (frovatriptan succinate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,096 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to this requirement for an election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration or election, the Director will issue a certificate of extension in U.S. Patent No. 5,464,864 for a period of 1,096 days. See 37 C.F.R. 1.785(b).

The period of extension would be 1,604 days, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 29, 2004 (69 Fed. Reg. 4305). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,186 - 7) + 1,015 \\ &= 1,604 \text{ days (4.4 years)}\end{aligned}$$

Since the regulatory review period began November 1, 1995, before the patent issued (November 7, 1995), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 1, 1995 to and including November 7, 1995 is 7 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,604 days, would extend the patent from November 7, 2012 to March 30, 2017, which is beyond the 14-year limit provided in 35 U.S.C. § 156(c)(3) (the approval date is November 8, 2001, thus the 14 year limit is November 8, 2015). The period of extension is thus limited to 1,096 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, November 7, 2012, to and including November 8, 2015, or 1,096 days.

Applicant has also filed an application for patent term extension for U.S. Patent No. 5,616,603 based upon the regulatory review of the product FROVA®. No more than one patent may be extended based upon the regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having

the earliest date of issuance unless applicant elects a different patent. Applicant is hereby REQUIRED TO ELECT a single patent for extension. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension will be granted to U.S. Patent No. 5,464,864.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

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| U.S. Patent No.: | 5,464,864 |
| Granted: | November 7, 1995 |
| Original Expiration Date ¹ : | November 7, 2012 |
| Applicant: | Gary T. Borrett et al. |
| Owner of Record: | Vernalis, Ltd. |
| Title: | Use of Tetrahydrocarbazone Derivatives as 5-HT ₁ -Receptor Agonists |
| Classification: | 514/468 |
| Product Trade Name: | FROVA® (frovatriptan succinate) |
| Term Extended: | 1,096 days |
| Expiration Date: | November 8, 2015 |

Any correspondence with respect to this matter should be addressed as follows:

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| By mail: | Commissioner for Patents Mail Stop Patent Ext. P.O. Box 1450 Alexandria, VA 22313-1450 | By FAX: (571) 273-7744 Attn: Office of Patent Legal Administration |
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Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.



Karin Ferriter
Senior Legal Advisor, Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: FROVA® (frovatriptan succinate)
FDA Docket No.: 03E-0147

Attention: Claudia Grillo

¹Subject to the provisions of 35 U.S.C. § 41(b).